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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,466	04/16/2004	William H. Andrews	SIER-022CON	1298

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EXAMINER	
NOBLE, MARCIA STEPHENS	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,466	ANDREWS ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-52 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4-8, 11, 16-18, 21, and 22 drawn to a method of enhancing TERT expression by inhibiting the GC Box-5 repressor binding site in vitro using a nucleic acid treatment, classified in class 424, subclass 93.1.

II. Claims 1,2, 4-7, 9, 11, 16, 17, 19, 21, and 22, drawn to a method of enhancing TERT expression by inhibiting the GC Box-5 repressor binding site in vitro using a protein treatment, classified in class 514, subclass 2.

III. Claims 1,2, 4-7, 10, 11, 16, 17, 20, 21, and 22, drawn to a method of enhancing TERT expression by inhibiting the GC Box-5 repressor binding site in vitro using a small molecule treatment, classified in class 514, subclass 1.

IV. Claims 1, 3-8, 11, 12, 16-18, 21, and 22, drawn to a method of enhancing TERT expression by inhibiting the GC Box-5 repressor binding site ex vivo using a nucleic acid treatment, classified in class 424, subclass 93.1.

V. Claims 1, 3-7, 9, 11, 12, 16, 17, 19, 21, and 22, drawn to a method of enhancing TERT expression by inhibiting the GC Box-5 repressor binding site ex vivo using a protein treatment, classified in class 514, subclass 2.

VI. Claims 1,3-7, 10-12, 16, 17, and 20-22, drawn to a method of enhancing TERT expression by inhibiting the GC Box-5 repressor binding site ex vivo using a small molecule treatment, classified in class 514, subclass 1.

VII. Claims 1,3-8, 11, 13, 16-18, 21, and 22, drawn to a method of enhancing TERT expression by inhibiting the GC Box-5 repressor binding site in vivo using a nucleic acid treatment, classified in class 514, subclass 44.

VIII. Claims 1, 3-7, 9, 11, 13, 16, 17, 19, 21, and 22, drawn to a method of enhancing TERT expression by inhibiting the GC Box-5 repressor binding site in vivo using a protein treatment, classified in class 514, subclass 2.

IX. Claims 1, 3-7, 10, 11, 13, 16, 17, and 20-21, drawn to a method of enhancing TERT expression by inhibiting the GC Box-5 repressor binding site in vivo using a small molecule treatment, classified in class 514, subclass 1.

X. Claims 11 and 14, drawn to a method for enhancing telomere expression in a cell wherein said method increases the proliferative capacity of said cell, classified in class 514, subclass 1.

XI. Claims 11 and 15, drawn to a method for enhancing telomere expression in a cell wherein said method delays senescence of said cell, classified in class 514, subclass 1.

XII. Claims 23, 24, and 26, drawn to method for decreasing telomere expression in a cell wherein said method administers an agent that

enhances GC-Box 5 TERT transcription repression ex vivo, classified in class 514, subclass 1.

XIII. Claims 23 and 25-29, drawn to a method for decreasing telomere expression in a cell wherein said method administers an agent that enhances GC-Box 5 TERT transcription repression in vivo using a nucleic acid, classified in class 514, subclass 44.

XIV. Claims 23, 25-28, and 30, drawn to a method for decreasing telomere expression in a cell wherein said method administers an agent that enhances GC-Box 5 TERT transcription repression in vivo using a peptide or protein, classified in class 514, subclass 2.

XV. Claims 31-33, drawn to method of treating a disease condition resulting from telomerase activity, classified in class 514, subclass 1.

XVI. Claims 34-44, drawn to a nucleic acid that has a sequence that is the same as or substantially identical to the GC-Box-5 repressor binding site and does not include the full minimal TERT promoter sequence, classified in class 536, subclass 23.1.

XVII. Claim 42-45, drawn to a DNA decoy sequence comprising a GC-Box 5 repressor binding site and a method of administering said decoy to cells, classified in class 514, subclass 44.

XVIII. Claims 46, 47 and 49, drawn to a method of determining whether an agent inhibits GC-Box 5 repression of TERT transcription in a cell free environment, classified in class 435, subclass 375.

XIX. Claims 46, 48, and 49, drawn to a method of determining whether an agent inhibits GC-Box 5 repression of TERT transcription in a cell, classified in class 435, subclass 375.

XX. Claims 50 and 51, drawn to cells comprising a telomerase gene modified by deletion of nucleotides in a CG-Box 5 repressor region, classified in class 536, subclass 23.1.

XXI. Claim 52, drawn to producing an antibody by from a B cell from a mammal that has induced, enhanced telomerase activity, classified in class 436, subclass 547.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, III, XVIII and IV, V, VI, XII and VII, VIII, IX, XIII, XIV, XV are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, groups of inventions I, II, III, XVIII and IV, V, VI, XII and VII, VIII, IX, XIII, XIV, XV are patentably distinct because the methods are done in different environments, in vitro, ex vivo, and in vivo. Methods done in these different environments will have different steps. For example, in vitro will only take place and involve an artificial system, whereas in vivo will involve treatment to a living organism, and ex vivo will involve a combination of both.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Inventions I, IV, VII, XIII and II, V, VIII, XIV and III, VI, IX are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, groups of inventions I, IV, VII, XIII and II, V, VIII, XIV and III, VI, IX are patentably distinct because they use different agents that have distinct biological functions. I, IV, VII and XIII use nucleic acids to promote protein production. II, V, VIII, XIV use proteins to have a more direct effect a compared to nucleic acids. III, VI, IX use small molecules which could have a large variety of chemical structures and accomplish the same function by other biological mechanisms.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Inventions I-XI, XVII and XII-XV are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, groups of inventions I-XI, XVII and

XII-XV are patentably distinct, because these methods produce antagonistic outcomes. I-XI, XVII enhance telomerase activity and XII-XV decrease telomerase activity.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inventions I-XV, XVII, XVIII, XIX, XXI and XVI, XX are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, groups of inventions I-XV, XVII, XVIII, XIX, XXI and XVI, XX are patentably distinct because the first group of inventions are methods and the later group of inventions are products that can be utilized in methods that are independent of the methods described in the first group. The nucleic acids of group XVI can be used to screen in various forms of genetic tests. The cells of XX can be used for basic research studies to gain insight into the effects of enhanced or decreased telomerase activity on cells.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Claims 7 and 17 link(s) inventions I-IX. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 8, 9, 10

and 18, 19, 20, respectively. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Claim 28 link(s) inventions XIII and XIV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 29 and 30. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER